REMARKS

Entry of the foregoing amendment, reconsideration and reexamination of the subject application, as amended, pursuant to and consistent with 37 CFR §1.112, and in light of the remarks which follow are respectfully requested. By the present amendments, Claim 1 has been amended to overcome the outstanding §1.112 issues. Also, Claim 1 has been amended to make absolutely clear that the claimed method is directed to a non-human animal model. Additionally, rejected Claims 38-48 and non-elected Claims 15-19, 29-32, 34-37 and 49-55 are cancelled in order to expedite prosecution.

Turning now to the Office Action, Claims 1-7, 11-14 and 38-48 stand provisionally rejected under the doctrine of obviousness-type double patenting. Essentially, the Examiner's position is that both this and the related applications claim method for testing the immune compatibility of cloned cells and tissues in an animal model which involve the formation of teratomas.

This rejection is moot with respect to Claims 38-48 (cancelled) and is obviated with respect to Claims 1-7 and 11-14 by the Terminal Disclaimer submitted herewith. Withdrawal of this rejection is respectfully requested.

Claims 1-7 and 11-14 stand rejected under 35 U.S.C. §1.112 first paragraph as not being adequately described or enabled based on the teachings of this application. This rejection is respectfully traversed to the extent that it may be applicable to the claims as amended.

At the outset, it is respectfully noted that Claim 1 has been amended to provide that nuclear transfer is effected under conditions that result in a non-human embryo. Essentially, the Examiner criticized the claims on two bases:

(i) the claims do not positively explicate an activation step; and

(ii) the specification does not provide "sufficient teaching or guidance" with respect to the evaluation of immune compatibility.

Both of these bases for rejection are respectfully traversed on the basis that they are improper. First, Applicant respectfully submits that it would be absolutely clear to one skilled in the art, in possession of the subject specification and claims, as amended, that the initial nuclear transfer step is effected under conditions that will result in the generation of an embryo.

Therefore, it would be readily understood that this process may include an activation step that promotes the development of the nuclear fusion unit into an embryo.

In further support thereof, the Examiner is respectfully advised that the subject application, with respect to the description of nuclear transfer, particularly incorporates by reference in its entirety US Patent 5,945,577, a patent exclusively licensed by the present Assignee. This patent clearly teaches that nuclear transfer methods typically include an activation step, and further describes that this may be effected by use of different methods including e.g., the application of different chemicals, alcohol, heat and the like. Additionally, this application clearly describes that the nuclear transfer procedures exemplified in Example 2 as being "described previously in Nature Biotechnology (1998) 16:2 642-646, herein incorporated by reference." This publication describes that nuclear transfer includes the activation of the NT unit by use of ionomycin and DMAP.

Therefore, when the claims are reasonably construed in view of the teachings of the specification, as is the appropriate legal standard, it is clear that an activation step is implicit or inherent to the claimed methods. If the Examiner insists, such an activation

step will be incorporated expressly in the claims (as this is clearly implicit to the claime0d and disclosed methods), and because such a limitation finds antecedent to support from the above-cited patent incorporated by reference.

With respect to the description of the means for determining whether an immune response is elicited against the grafted cells or tissue, the specification clearly describes various well known means for evaluating immune responses to transplanted tissues or cells, e.g., assaying for cytotoxic T-lymphocyte responses, evaluating whether transplanted cells or tissues are stably maintained over time, and screening for antibodies against antigens expressed by the transplanted cells or tissues. (see e.g. the paragraph bridge on pages 8-9 of the specification, p. 10, line 6, 18-25, et al..)

Therefore, it is respectfully submitted that based on the teachings of the application, one skilled in the art would readily understand that immune compatibility can be evaluated by a variety of different means and including those specifically disclosed, e.g., measuring CTL responses, assaying for antibodies to transplanted cells and assaying the stability of the transplanted cells or tissues in the transplant recipient over prolonged time.

Therefore, based on the foregoing, withdrawal of the §1.112 first paragraph rejection of claims 1-7 and 11-14 is respectfully requested.

Claims 38-40, 44-47 and 42 further stand rejected based on §102(b) over Anderson et al., Hibbs [Am. J. Vet. Rev. 29:1291-94 (1162)]. These rejections are moot as these claims have been cancelled without prejudice to expedite prosecution.

It is anticipated that this Response will place this case in condition for allowance. A Notice to this effect is respectfully solicited.

However, if the Examiner has any questions relating to this Reply, he is hopefully requested to contact the undersigned.

Respectfully submitted,

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